EXHIBIT C

In the Matter of:

FTC, et al. v. Quincy Bioscience Holding, et al.

October 20, 2021
David Katz, M.D., MPH - Confidential

Condensed Transcript with Word Index

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and THE PEOPLE OF THE STATE OF NEW YORK, BY LETITIA JAMES, ATTORNEY GENERAL OF THE STATE OF NEW YORK, Plaintiffs, vs. QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation, et al., Defendants.	)))))))))	Case No. 1:17-cv-00124-LLS

CONFIDENTIAL - ATTORNEYS' EYES ONLY

Wednesday, October 20, 2021, Via Zoom Videoconference

The above-entitled matter came on for deposition, pursuant to notice, at 9:30 a.m., for the testimony of:

DAVID KATZ, M.D., MPH

Reported by: Deborah Wehr, RPR

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APPEARANCES:

ON BEHALF OF PLAINTIFFS:
ANNETTE SOBERATS, ESQUIRE
EDWARD GLENNON, ESQUIRE
ANDREW WONE, ESQUIRE
WILLIAM DUCKLOW, INVESTIGATOR
DAVID OVADIA, ECONOMIST
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20850
(202) 326-3148
annette.soberats@ftc.gov

KATE MATUSCHAK, ESQUIRE
Attorney General of the State of New York
Consumer Frauds and Protection Bureau
28 Liberty Street
New York, New York 10005
(212) 416-6189
kate.matuschak@ag.ny.gov

(Appearances continued on next page.)

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(Appearances continued.)

ON BEHALF OF CORPORATE DEFENDANTS:
GEOFFREY W. CASTELLO, ESQUIRE
JACLYN M. METZINGER, ESQUIRE
GLENN GRAHAM, ESQUIRE
CAITLIN R. HICKEY, ESQUIRE
Kelley Drye & Warren, LLP
101 Park Avenue
New York, New York 10178
(212) 808-7800
gcastello@kelleydrye.com

ON BEHALF OF DEFENDANT UNDERWOOD:
MICHAEL B. de LEEUW, ESQUIRE
TAMAR S. WISE, ESQUIRE
Cozen O'Connor
45 Broadway Atrium
Suite 1600
New York, New York 10006
(212) 908-1331
mdeleeuw@cozen.com

ALSO PRESENT:
ERIC VAVRASEK, VIDEOGRAPHER

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I N D E X

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nutraceuticals and evidence-based integrative medicine practice. Can you give me examples of some of the nutraceuticals that you most widely used during the 15 years that you were at the Integrative Medicine Center?

A. These were highly personalized to address individual patient concerns. So all I can do to be efficient here would offer a representative list, but curcumin was routinely used as an anti-inflammatory. Concentrated omega 3s were used as anti-inflammatories and to ameliorate autoimmune disease. Glycyrrhiza was routinely used as a slight stimulant for blood pressure, some use in people with something called orthostatic hypotension. A number of nutraceuticals and botanicals were used to facilitate sleep and alleviate anxiety. Among those we made use of most routinely was L-theanine which is a modified amino acid. Echinacea was used sometimes as an immune stimulant to help people who had frequently recurring viral infections. Lysine was used as a suppressant for recurrent herpes simplex. Coenzyme Q10 was used routinely for support of cardiac function. I can keep going, but a wide array of personally directed nutraceuticals often in combination with one another, often in combination with pharmacotherapy and other

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modalities.

Q. Were any of the nutraceuticals that you used at the Integrative Medicine Center intended for memory or cognitive impairment?

A. Probably so. Certainly there were people who were interested in enhancing cognition and asked questions about availability of products to help with that. So in the mix was the use of various things to support cognitive function, although generally, the focus there was on overall aspects of health that potentially contributed to brain function. So circulation, for example. And the use of nutraceuticals to support cognition would sometimes be what we might call indirect. So by addressing enhanced circulatory health, you are enhancing the function of all body organs, brain included.

Q. Can you give me a couple of examples of nutraceuticals that you would have recommended for memory or cognitive improvement during this time?

MR. CASTELLO: Objection.

THE WITNESS: You are asking what I would have recommended and you noted in your introduction that this was team care. So very often the specific recommendations for nutraceuticals came from naturopathic colleagues seeing the same patient at the

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same time. As the senior physician, I needed to approve all such recommendations. We essentially managed patient care jointly, and I signed off on all the cases.

So examples would include some of the compounds I already mentioned. Omega 3 is in particular one of the prevalent, omega 3 fatty acids, docosahexaenoic acid is concentrated in the brain as associated with both mood stability and cognitive function. We used that routinely. B complex is associated with neuronal activity. So B6, B12 and sometimes the full suite of B vitamins were used. Arginine is an amino acid that is a precursor to nitric oxide which facilitates vasodilation, enhances blood flow. That was in the mix and a range of many others.

BY MS. SOBERATS:

Q. Thank you. It is my understanding that the Integrative Medicine Center ceased operations in November of 2014; is that correct?

A. I recall it being approximately 2015, but November 2014 certainly wouldn't be far wrong.

Q. And why did it close?

A. The cost of this care model was very high, and the hospital essentially was pushing for a more profitable model of care. Seeing very difficult,

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challenging patients who more often than not have been everywhere, tried everything, still needed help in a team care model was obviously not compatible with the prevailing reimbursement for medical care in the United States. We were often left to bill patients out of pocket, but we wanted to help patients who really couldn't afford this model of care. So historically, the Integrative Medicine Center lost money for the hospital. So they were tired of carrying the economic burden. They no longer had the time, because my career was shifting more toward aspects of public health, to devote to trying to create new means of making the Integrative Medicine Center more profitable. So we agreed that it had run its course after the better part of 15 years.

Q. Dr. Katz, have you obtained a degree in statistics?

A. No.

Q. Have you completed any coursework or training in statistics?

A. Yes.

Q. Can you describe that for me?

A. A master's in public health involves fairly extensive training in biostatistics. In my case, I focused especially on statistical elements useful for

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me in the clinical research career. I was trained in SAS programming language and trained in routine methods of biostatistics and actually went on to become the course director in biostatistics for Yale medical students for roughly a decade and have coauthored now five editions of a textbook on epidemiology, biostatistics, preventive medicine in public health.

Q. You mentioned you were the course director of biostatistics at the Yale University School of Medicine. Do you actually -- did you actually teach biostatistics courses while you were at Yale?

A. I don't understand the question.

Q. Did you teach biostatistics courses while you were at the Yale School of Medicine?

A. I'm sorry, I don't understand the question. I taught biostatistics at the Yale School of medicine. But you mean while I was a student?

Q. No, no, you have answered my question. I understand your answer. Did you teach seemingly unrelated regressions in that class?

A. No.

Q. And were you -- did you cover seemingly unrelated regressions while you were undergoing your biostatistics training as part of your master's of public health program?

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A. I don't recall ever encountering that method at that time.

Q. Do you have any academic appointments at Yale currently?

A. No.

Q. In what year was your last academic appointment at the Yale School of Medicine?

A. I stepped down -- the final position I held was director of the Yale University Prevention Research Center, and I stepped down in 2019 to run my own company.

Q. Do you have any appointments at Yale currently?

A. No.

Q. And were you ever a full professor at Yale?

A. No.

Q. Have you obtained a degree in economics?

A. No.

Q. Have you obtained any coursework or training in econometrics?

A. Coursework, it's possible. I did take economics as an undergraduate, and that may have figured in the content, but to be honest, it was a very long time ago.

Q. Do you have a law degree?

A. No.

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Q. Have you obtained a degree in biochemistry?

A. No.

Q. Did you complete any coursework or training in biochemistry?

A. Yes.

Q. Can you describe that for me.

A. Biochemistry is a requirement in medical school.

Q. How many semesters of biochemistry did you obtain during medical school?

A. I don't recall.

Q. Outside of medical school, have you completed any coursework or training in biochemistry?

A. Chemistry per se, which included some biochemistry, was a premedical requirement as well.

Q. And you --

A. In my case --

Q. You would have fulfilled that in your undergraduate studies?

A. I was going to say in my case, I think I fulfilled it in an AP course in high school.

Q. Okay. What specific training do you have in the field of memory or cognition?

A. The training that any medical student and internal medicine trainee would receive, a general

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understanding of neuroanatomy, neurophysiology, the anatomy of the brain, the mechanisms of short-term and long-term memory, pathophysiology that can impair those.

Q. Do you belong to any professional organizations in the field of memory or cognition?

A. Not per se.

Q. Do you belong to any professional organizations in the field of statistics?

A. Again, not per se.

Q. Have you ever conducted any clinical trials involving treatment of memory loss or cognitive decline?

A. Never as the primary study focus.

Q. Have you ever conducted any clinical trials examining how a protein is digested in the human body?

A. No.

Q. Have you ever conducted any clinical trials involving the gut-brain access?

A. Arguably, yes. We conducted studies of probiotics and were looking at potential systemic effects at least once, possibly twice. So the gut-brain access --

Q. When you say at least once or twice, are you referring to one or two studies?

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to recommend that universally. Whether or not you can get everybody to do it is another story.

Q. I would like to move on to the SUR analysis. Is SUR an econometric model?

A. It can be used in econometrics. I don't know that that is the limitations of its use. Can it be an econometric model? Is that what you are asking or did it originate as an econometric model?

Q. I understand your point. I think I can move on, actually. And just to be clear for the record, when I say SUR, I'm referring to the seemingly unrelated regressions model.

A. Yeah, I recognized that as opposed to suddenly getting more formal with me.

Q. In your opinion is SUR a method for correcting for multiplicity?

A. That's not my understanding, no.

(Katz Deposition Exhibit Number DK-14 was marked for identification.)

BY MS. SOBERATS:

Q. I have just revealed a new exhibit which has been marked as Exhibit DK-14. This is titled Exhibit B, Madison Memory Study: An Expanded Analysis. And the authors are J. Howard Beales, III, Janet Liang, Ph.D., and Robert Fenili, Ph.D., and it is dated

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July 18, 2019. Have you seen this document before?

A. I have.

Q. And the seemingly unrelated regression analysis that you referred to in your report is contained within this paper, correct?

A. Yes, this was the reference. This and direct conversation with Dr. Beales.

Q. Did you ever have discussions with Dr. Beales about the SUR analysis outside presence of counsel?

A. No.

Q. Can you turn to page 5 of this paper, Exhibit DK-14. And there are two tables listed here, Table 2.1 and Table 2.2. And they report F values. Do you see that?

A. Yes.

Q. What is an F test in the context of this paper?

A. I profess no specific expertise in this analytical method. But the statistic in this case, the F statistic in the case of T tests, T statistic is essentially some critical ratio of effect that is used as the basis to determine statistical significance. So with any given analytical test, you generate some quantity. It may relate to error terms. It may relate to the primary effect terms. It may relate to a ratio of observe to expected as in chi-square testing. There

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are many different test statistics across the expanse of hypothesis and they'll take many different numerical forms. So the F statistic is one of those. It is apparently the one that emanates from seemingly unrelated regression, which is a technique I have never used and do not know intimately.

And then that statistic is interpreted in light of the analysis run, which usually involves things like degrees of freedom to generate the threshold of statistical significance.

Q. Now -- were you done?

A. I'm sorry, I was going to say the associated statistical significance is in the column in both Table 2.1 and 2.2.

Q. That's Pr less than F column?

A. Probability, that's right.

Q. And do you agree that the F values reported in these two tables do not indicate whether Prevagen outperforms placebo or vice versa?

A. I would have to spend a lot more time working on the details of these tables. I think, frankly, they are quite abstruse. We see a whole host of statistically significant test statistics here. So we would have to spend time attempting to interpret that. I can't give you an answer.

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Q. Do you agree that you would need to assess the individual Cogstate task to determine the magnitude of the treatment effect for each task?

A. Do I agree that you would need to study a given task to determine the magnitude of treatment effect for that specific task?

Q. Yes.

A. That makes sense, sure.

Q. Let's go back to your report. This is Exhibit DK-1. And I would like you to turn to page 18 of the PDF, which is page 16 of your report. I would like you to turn to paragraph 35. Here you state, "We have also reviewed the 'seemingly unrelated regression' analysis. That analysis based on the full array of cognitive measures produces decisively significant results for those study participants without overt cognitive impairment." Do you see that?

A. I do.

Q. And you relied upon the SUR analysis reported in Exhibit DK-14 to reach that opinion, correct?

A. And additional guidance from Dr. Beales to help me understand it.

Q. What guidance from Dr. Beales did you receive to help you understand this?

A. Our discussions were about the general utility

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of the method, what it was used to do. It was certainly not a tutorial in how to conduct it independently, but why he did it, why he thought it was relevant, what results he, as an expert in the method, thought it produced. I was guided in this particular matter by his expertise.

Q. Would you have been able to reach the opinion you express here without speaking with Dr. Beales?

A. A related conclusion just by reading the paper that this enhanced the conviction that there was an important therapeutic effect by aggregating across components of the Cogstate, but I think somewhat less emphatic than stated here because, again, I received additional insights directly from the source that helped to inform my determination.

Q. When you spoke with Dr. Beales, did you review any other documents related to his SUR analysis?

A. Not that I recall.

Q. Do you agree that this SUR analysis is a post hoc analysis of the Madison Memory Study data?

MR. CASTELLO: Objection.

THE WITNESS: I think that's difficult to answer, because as you noted earlier today, there's reference to the Cogstate battery of tests, and if we want to get the terminology just right, we'll have to

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go back to the protocol document again. But there's reference to the Cogstate software and there is no explicit mention in the protocol of using only one component of the Cogstate battery of tests. By implication, then, one presumes you are going to use them all. And that begs the question how are you going to put them together. Admittedly, the protocol didn't tell us what analytical technique would be used to aggregate those component measures into the single parent measure. But there certainly was at least the suggestion that the single parent measure was of interest.

BY MS. SOBERATS:

Q. And scrolling back to page 1 of Exhibit DK-14, which contains the SUR analysis, you see that it's dated 2019, correct?

A. I see that.

Q. And so this analysis was conducted after the data for the Madison Memory Study was examined, correct?

A. I don't recall the exact date the data were examined. I don't know that I was involved in that, but that's my understanding, yes, this was after.

Q. If you can scroll back to your initial expert report, that's Exhibit DK-1, and I would like you to

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scroll to page 28 of the PDF, which is page 26 of your report, and if you could navigate to paragraph 61.

A. I'm actually seeing that on page 27.

Q. Just a moment. Okay. In paragraph 61, you write, "Thus, the expected movement in one relative to the other would not be an independent measure but a confirmatory one. Similarly, measures of different dimensions of cognitive function are likely to be highly correlated. The 'seemingly unrelated regression' approach is a more appropriate method to deal with related measures as opposed to the Bonferroni correction." Is it your opinion that SUR and the Bonferroni correction are mutually exclusive statistical techniques?

A. No, not within the context of the given study. No, rather the opposite. It's my impression they do very different things.

Q. And what issue does the Bonferroni correction account for?

A. It's a correction for multiplicity, testing multiple hypotheses or using multiple independent outcome measures in the same study. I won't embellish, but I certainly could imagine a study that would warrant something like a SUR analysis and a Bonferroni.

Q. Thank you. If you could turn back to Exhibit

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DK-14, and scroll to page 2 of that exhibit which is also -- page 2 of the PDF, which is also page 2 of the exhibit, in the first sentence of section 2 which is titled Mixed-Effect Seemingly Unrelated Regression Model, the author states, "In previous analyses, the nine measures of cognitive efficacy were analyzed separately for each group. These tests were done under the assumption that each measure was independent of other measures." Do you see that?

A. I do.

Q. Do you agree that in prior analyses of the Madison Memory Study, the nine Cogstate measures were analyzed separately for each subgroup?

A. They were analyzed separately, yes.

Q. And do you agree that in prior analyses of the Madison Memory Study, the researchers assumed each of the nine Cogstate measures were independent of the other measures?

A. I don't have any basis to reach that conclusion.

Q. Going back to your expert report, Exhibit DK-1, I would like you to turn to page 18 of the PDF, which is page 16 of your report. And if you could navigate to paragraph 36, here you state, "The analysis also shows a dose-response curve seen for the full array and

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for many of the individual test components of that array." Do you see that statement?
A. I do.
Q. What do you mean by dose-response curve in this context?
A. Generally a greater effect with increased exposure to the treatment, in this case, Prevagen. So for example, if you are looking at curves to represent treatment response versus response in a control group, hit those curves splay over time, and that would be consistent with a dose response. Obviously, another expression of this would be a study that willfully tests different doses of a given compound. That was not done here.
MS. SOBERATS: Can we go off the record for a moment.
THE VIDEOGRAPHER: We are going off the record at 5:00 p.m.
(A recess was taken.)
THE VIDEOGRAPHER: We are going back on the record at 5:13 p.m.
BY MS. SOBERATS:
Q. Dr. Katz, are you rendering an opinion about whether Quincy has sufficient evidence to substantiate its advertising claims?

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MR. CASTELLO: Objection.
THE WITNESS: No, not specifically.
BY MS. SOBERATS:
Q. Do you consider yourself an expert in the AD8 questionnaire?
A. No.
Q. Do you consider yourself an expert in neuropsychology?
A. No.
Q. Do you consider yourself an expert in cognitive impairment?
MR. CASTELLO: Objection.
THE WITNESS: I'm tempted to go with I hope not. You know, it's a relevant consideration for anyone practicing internal medicine. So I don't have dedicated expertise in that area. I have, if you will, the generalist's expertise. It's a condition I need to address or needed to address as a clinician.
BY MS. SOBERATS:
Q. And do you consider yourself an expert in memory?
MR. CASTELLO: Objection.
THE WITNESS: I don't really know how to interpret that. I understand the importance of it, the impact it has on patients, and once again, it falls or

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rather fell within my clinical purview. But I'm not someone who has devoted a career to the study of memory.
BY MS. SOBERATS:
Q. Do you consider yourself to be an expert in statistics or biostatistics?
A. More than many, less than some.
Q. Going back to Exhibit DK-14, I would like you to turn to page 5 of this exhibit. The very first paragraph on that page states, "There are no statistically significant differences between the treatment and control groups in the time pattern of score improvements (Model x Arm x Time)." Do you see that?
A. I do.
Q. I'm trying to understand how that statement is consistent with your statement that there is a dose-response curve according to this analysis. I read those two statements to be contradictory. Can you explain how there's evidence of a dose-response curve in light of this statement that there are no statistically significant differences between the treatment and control groups in the time pattern of score improvements?
A. What I interpret this to mean is that time did

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not alter the relationship between the treatment arm and the other elements of the model. So the general slope of change was established by the particular treatment. But without looking at specific curves and getting into details here, to me it begs questions about the slope of change. But this is what it indicates, that there isn't a meaningful change in the slope of the curves.
So for example, if you had a treatment effect which was modest but consistent for some period of time, a month, six weeks, and then suddenly took a dramatic departure and the pace of improvement rapidly accelerated or decelerated, there would be an independent effect of time on the slope of the curve. This statement to me indicates that that was not observed.
Q. What information -- moving on to another topic, you discussed Aduhelm and its approval in your rebuttal report. I want to ask you a few questions about that. What information did you review in preparing your statements relating to Aduhelm for your expert rebuttal report?
A. Little other than the mainstream media coverage of FDA decisionmaking in reversals. My primary source, since this was not until recently an FDA-approved

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CERTIFICATION OF REPORTER
DOCKET/FILE NUMBER: 1:17-cv-00124-LLS
CASE TITLE: FTC and THE PEOPLE OF THE STATE OF NEW YORK v. QUINCY BIOSCIENCE HOLDING COMPANY, INC., et al,
DATE: OCTOBER 20, 2021

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: 10/27/2021

s/Deborah Wehr
DEBORAH WEHR, RPR

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CERTIFICATE OF WITNESS

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

I hereby certify, under penalty of perjury, that I have affixed my signature hereto on the date so indicated.

DATED: _____
DAVID KATZ, M.D., MPH

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WITNESS: DAVID KATZ, M.D., MPH
DATE: OCTOBER 20, 2021
CASE: FTC v. QUINCY BIOSCIENCE, ET AL.
Please note any errors and the corrections thereof on This errata sheet. The rules require a reason for any Change or correction. It may be general, such as "To Correct stenographic error," or "To clarify the Record," or "To conform with the facts."

PAGE	LINE	CORRECTION	REASON FOR CHANGE